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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,294	12/28/2001	Jean Marie Vogel	9676-311	2836

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,294	VOGEL ET AL.	
	Examin r	Art Unit	
	Humera N.Sheikh	1615	

-- The MAILING DATE of this communication app ars n th cover sheet with the correspond nc address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003 (paper no.6)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *5-7,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-16,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Applicant's election with traverse of the Restriction/Election Requirement filed 02/26/03 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that "microparticles or microspheres coated with autologous cells are not mutually exclusive with those comprising cell adhesion promoters." This is not found persuasive because the microparticles can be coated with either autologous cells or with a collagen (or a derivative thereof) or glucosaminoglycans (or a mixture thereof). The coatings are distinct and therefore are capable of providing distinct results.

The requirement is still deemed proper and is therefore made FINAL.

Claims *5-7, 17 and 18* have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 1-4, 8-16, 19 and 20 are pending. Claims 5-7, 17 & 18 have been withdrawn. Claims 1-4, 8-16, 19 and 20 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 8-16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajagopalan et al. (US Pat. No. 5,843,987) in view of Boschetti et al. (US Pat. No. 5,635,215).

Rajagopalan teaches a method for treating gastroesophageal reflux disease (GERD), which comprises parenterally administering particles of ellagic acid, which is known to be useful for the treatment of gastrointestinal disorders, such as GERD, to a human or other animal (see reference column 1, lines 1-18); (col. 2, lines 21-57); (col. 5, lines 15-42); examples and claims.

According to Rajagopalan, ellagic acid has prokinetic activity, and therefore stimulates motility of the gastrointestinal tract, enhances esophageal contractility,

gastric emptying and small intestine transit time. Furthermore, ellagic acid is useful in the treatment of constipation, heartburn, non-ulcer esophagitis, GERD, esophagitis, gastric ulcers, and/or duodenal ulcers (col. 2, lines 25-35).

The method of treatment can be accomplished by administration of ellagic acid in various suitable unitary dosage forms, such as orally, parenterally, or rectally. Oral liquid dosage forms include suspensions, syrups, elixirs and solutions. Solid dosage forms include powders, pills, compressed tablets, hard capsules containing beads or particles of ellagic acid or soft gelatin capsules. Oral dosage forms can also be film coated. For parenteral dosage forms, acceptable carriers include sterile water, saline solution, glucose solution or mixtures of saline and glucose solutions (col. 5, lines 26-42).

The examples at columns 10-12 demonstrate various dosage forms, such as oral solutions, suspensions and parenteral solutions. Example 5 demonstrates the teaching of a parenteral solution of ellagic acid in combination with propylene glycol, chlorocresol and water for injection.

What is lacking in Rajagopalan is collagen (or a derivative thereof) or glucosaminoglycans as the particular coating material of the microparticles.

Boschetti ('215) teaches microspheres and injectable solutions comprising a hydrophilic copolymer coated with a cell adhesion promoter, wherein different types of cell adhesion promoters, include, collagen, gelatin, glucosaminoglycans, lectins, polycations, or any other synthetic biological cell adhesion agent and wherein the

presence of a cationic charge on the surface of the microspheres makes it possible to initiate and improve cell adhesion (see reference column 1, line 46 through col. 2, line 42).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydrophilic copolymer coatings, that are coated with cell adhesion agents (i.e., collagen, glucosaminoglycans) as taught by Boschetti with the injectable particles of Rajagopalan because Boschetti teaches that the microspheres hydrophilic character enables them to be placed in suspension, without formation of aggregates nor adhesion to the walls of the catheters, syringes, needles and other materials used in embolization and similarly Rajagopalan teaches parenteral administration of particles, specifically of ellagic acid for the treatment of gastrointestinal reflux disease. The expected result would be a hydrophilic-coated formulation comprising injectable particles for the treatment of various gastrointestinal disorders.

Regarding the administration of the microparticles into the lower esophageal sphincter or diaphragm, the prior art (Rajagopalan) teaches parenteral administration of particles into the gastrointestinal tract. The gastrointestinal tract as used therein, includes the entire digestive tract, including the esophagus, stomach, small intestine, large intestine, and the colon (see col. 4, lines 64-67). Furthermore, one of ordinary skill in the pharmaceutical art could determine a suitable means and route of administration based on the intended locality of treatment. There is no criticality seen in the particular

area of administration since the prior art teaches the administration of particles into the gastrointestinal tract for the treatment of gastro-related diseases.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
May 13, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600